

OFFICE OF SPECIAL MASTERS

No. 99-431V

September 26, 2006

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REBECCA S. KELLER, \*

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Petitioner, \*

\*

v. \* Hepatitis B vaccine followed

\*

one or two days later by

SECRETARY OF THE DEPARTMENT OF \* CIDP; causation?

HEALTH AND HUMAN SERVICES, \*

\*

Respondent. \*

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**ORDER TO SHOW CAUSE**<sup>1</sup>

Petitioner filed a petition under the name Rebecca S. McCauley on July 2, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that she received hepatitis B vaccine on January 2, 1998, January 30, 1998, and July 10, 1998. Petition, ¶ 3. Her adverse reaction was ultimately described as chronic inflammatory demyelinating polyneuropathy (CIDP).

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<sup>1</sup> Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Petitioner had chronic inflammatory demyelinating polyneuropathy (CIDP) whose onset was either the day after her third hepatitis B vaccination, Friday, July 10, 1998, or two days after the vaccination. On July 13, 1998, she gave this history after the vaccination: “The following evening, she had a severe left-sided headache with visual aura symptoms.” Med. recs. at Ex. 1, p. 20. Petitioner had a history of migraine headaches. On Sunday, July 12, 1998, two days after vaccination, her right hand was weak, she had complete right wrist drop, and her right arm felt very cold from the elbow down. *Id.* Subsequently, petitioner was diagnosed with CIDP. Numerous records ascribe causation to the third hepatitis B vaccination. Petitioner, a licensed practical nurse, won her workmen’s compensation proceeding on the basis that hepatitis B caused her CIDP. Med. recs. at Ex. 13, p. 10.

Petitioner is ORDERED TO SHOW CAUSE by **November 3, 2006** why this case should not be dismissed.

## **DISCUSSION**

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]” the logical sequence being supported by “reputable medical or scientific explanation[.]” *i.e.*, “evidence in the form of scientific studies or expert medical testimony[.]”

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said “we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...”

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6<sup>th</sup> Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had CIDP, but also that the vaccine was a substantial factor in bringing about her CIDP. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. March 30, 2006), the undersigned ruled that hepatitis B vaccine can cause GBS and CIDP, and did so in that case. The onset interval after hepatitis B vaccination was three weeks. Respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute demyelinating reaction, would be a few days to three to four weeks. Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525, at \*15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006).

Here, petitioner's onset of headaches and visual aura was one day. The onset of right hand and wrist weakness was two days. Either one or two days is too soon an onset to put petitioner in the temporal framework that respondent's Dr. Martin conceived was barely

appropriate for a demyelinating reaction to vaccination. Petitioner must file a medical expert report supporting that hepatitis B vaccine caused petitioner's CIDP either one or two days later. (It is difficult at present for the undersigned to determine if petitioner's onset of headache and visual aura a day after the third hepatitis B vaccination was the onset of her CIDP or if the onset was the second day when she had a weak right hand.)

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **November 3, 2006.**

**IT IS SO ORDERED.**

September 26, 2006

DATE

s/ Laura D. Millman

Laura D. Millman

Special Master